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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,516	01/31/2001	Balkrishna S. Jadhav	687-430	9340

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EXAMINER	
ISABELLA, DAVID J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/774,516	JADHAV, BALKRISHNA S.	
	Examiner	Art Unit	
	DAVID J ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14 and 46-81* is/are pending in the application.

4a) Of the above claim(s) *54-58 and 61-65* is/are withdrawn from consideration.

5)☒ Claim(s) *86* is/are allowed.

6)☒ Claim(s) *8-14,46-53,59,60,66-71 and 73-85* is/are rejected.

7)☒ Claim(s) *72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Applicant's arguments filed on 11/19/2004 have been considered but remains unpersuasive. Applicant argues that the inventive stent is directed to a preparation of bioabsorable materials having stable and predictable characteristics. Applicant argues that the stent as claimed has improved resistance to hydrolytic decomposition. For the record, claim 46 is directed to a bioresorbable self expanding stent consisting of a blend of two bioresorbable homopolymers. Nowhere in these claims are there any recitation or limitation to the features that supports applicant's arguments. The broad recitation of "stent" in the preamble, may broadly be interpreted to include a device that has application including tubular articles used in osteointegration procedures. Moreover, applicant's arguments directed to the language of "consisting essentially of" is found only in independent claim 46. The other independent claims remain open ended. Brenneman et al discloses the use of homopolymers used in the manufacture of self expanding urethral stents. While the stent is not formed from a blend of the homopolymers, the art clearly recognizes the benefits in using blends, including better extrusion and molding characteristics, improved crazing and flexibility as well as improved in vivo properties (dimensional stability,strength, stiffness/flexibility and breaking strength. Examiner need not to show or meet applicant's objectives but only provide a reasonable motivation to one with ordinary skill in the art to use a blend of homopolymers in manufacturing stents.

Currently claims 8-14,46-53,59,60,66-72,76-81 are pending for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-14,46,59,60,66-71,76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5160341) in view of Kaplan et al (5320624) or Liu (5997568) and Cooper, et al.

Claim 46 simply requires a tubular shaped member having first and second ends consisting essentially of a blend of two homopolymers. The stent is sized so has to have a non-compressed diameter of 12 to 18 mm.

Brenneman et al discloses a bioresorbable, self expanding stent comprising a tubular shaped member having first and second ends, the member being formed from biocompatible homopolymers and the stent having a non-compressed diameter of 12mm (36 French). Brenneman et al lacks only the disclosure of using a blend of two homopolymers.

Kaplan, et al and Liu teach the use of blends of lactides homopolymers and caprolactone homopolymers in the manufacture of absorbable surgical devices including filaments and woven articles. Cooper, et al discloses an absorbable polymer blends useful to manufacture medical devices including stents (see column 5, lines 63-67 and column 6, lines 1-27. The polymer blends include at least two homopolymers including poly-L-lactide and poly-epsilon-caprolactone (see column 1, lines 27-39).

The use of homopolymer blends and their unique properties were not evident in the art until after the patent to Brenneman et al. It is clear that the advantages in utilizing homopolymer blends in the fabrication of various medical articles were well known to one with ordinary skill in the art at the time of applicant's invention. The ratio of the blend of the two homopolymers can be varied depending upon the desired physical properties. Examiner maintains that at the time of the invention, the broad concept of claim 46 was obvious to one of ordinary skill in the art. Liu and Kaplan, et al both teach broadly of using two homopolymers including lactide and capralactone in manufacturing surgical devices. Brenneman et al teaches that homopolymers were well known at the time for it's use in the manufacturing of self-expanding urethral stents having a non-compressed diameter of 12mm. Clearly at the time of the invention, it was known to blend homopolymers in selected proportions depending on the desired physical properties. Claim 46 lacks any recitation to the particulars of the desired physical properties. The only reference to a specific property is that the article be self-expanding. This property is shown and realized prior to applicant's invention by Brenneman et al. Contrary to applicant's arguments, Brenneman et al and Cooper, et al

recognized the use of homopolymers in the manufacture of various surgical articles including stents/filaments. Applicant's arguments concerning the preferred examples are not persuasive. Clearly, at the time of the invention, the blending of two homopolymers, as broadly claimed, was recognized and disclosed by each of Liu and Kaplan, et al.

Claim 60, see ratio as disclosed in Kaplan, et al and Liu.

Claims 8-14,46-53,59,60,66-71,76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5160341) as modified further in view of Stinson (6245103).

Claims 47,49-53,11-14 the specifics to the structure, dimensions and mechanical characteristics of helically wound stents is taught by Stinson. (Note, the diameter of the stent is disclosed by Stinson, see Table 7.) To fabricate a helically wound stent from the polymers blend as disclosed by Cooper et al as modified by Kaplan et al would have been obvious to one with ordinary skill in the art based upon the desired stent characteristics that are required to meet the in vivo demands of the particular patient.

Claim 47, see braided tubes as shown in the figures of Stinson.

Claim 48, see Kaplan,et al and Liu.

Claim 49, from table 7, see example 30 of Stinson.

Claim 50, the ratio as disclosed by applicant's specification falls within the same ratios as disclosed by Kaplan. Therefor the modulus of the Kaplan's device as modified by Stinson would inherently fall within the range as claimed by applicant.

Claim 51, see range as disclosed by Stinson.

Claim 52, see table 7 of Stinson.

Claim 53, see crossing angles as taught by Stinson (column 10).

Claim 59, the stent of Kaplan has the size and physical characteristics as claimed by applicant and would inherently suffice (ie meet the requirements for use in the urethra) as a urethral stent.

Claim 60, see ratio blend as disclosed by Kaplan

Claims 8 and 9, see structure of the device as illustrated by Stinson.

Claims 10,66,67,68, see homopolymers of Liu and Kaplan, et al.

(Claim 66, see column1, lines 27 of Cooper et al; and claim 67, see columns 4 and 5 of Cooper et al.)

Claims 69-71, see column 3, lines 16+ of Cooper et al.

Claims 76-79, see the rejection to claims supra. Claim 76 is open ended and does not require only two homopolymers.

Allowable Subject Matter

Claim 72 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 81 is allowed.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that the art fails to show the combination of a bioresorbable stent and a blend of homopolymers. This argument is moot in light of the new ground of rejection as applied supra. Examiner maintains that to manufacture a "stent", as broadly set forth in the claim, from a blend of homopolymers would have been obvious to one with ordinary skill in the art as homopolymers blends were known in the manufacture of various surgical and medical devices

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
February 2, 2005